



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ron S. Israeli et al.

Serial No.: 08/466,381 Group Art Unit: 1647

Filed: June 6, 1995 Examiner: S. Gucker

For: PROSTATE-SPECIFIC MEMBRANE ANTIGEN AND USES THEREOF

1185 Avenue of the Americas New York, New York 10036

March 5, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

**RECEIVED** 

Sir:

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#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

This Supplemental Information Disclosure Statement is submitted under 37 C.F.R. §1.97(c)(2) to supplement the Information Disclosure Statements filed on July 11, 1997, March 20, 2000, October 20, 2000, January 19, 2001, August 8, 2001, February 21, 2002 and May 7, 2002 in connection with the above-identified application.

In accordance with their duty of disclosure under 37 C.F.R. \$1.56, applicants direct the Examiner's attention to the following references which are listed on the attached PTO-1449 form (Exhibit A), and attached hereto as Exhibits 1-58:

- 1. U.S. Patent No. 5,672,592, issued September 30, 1997 to Paul F. Jackson and Barbara S. Slusher (Exhibit 1);
- U.S. Patent No. 5,795,877, issued August 18, 1998 to Paul
   F. Jackson et al. (Exhibit 2);
- 3. U.S. Patent No. 5,804,602, issued September 8, 1998 to Barbara S. Slusher et al. (Exhibit 3);
- 4. U.S. Patent No. 5,863,536, issued January 26, 1999 to PaulF. Jackson et al. (Exhibit 4);
- 5. U.S. Patent No. 5,880,112, issued March 9, 1999 to Paul F. Jackson et al. (Exhibit 5);

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- 6. U.S. Patent No. 5,902,817, issued May 11, 1999 to Paul F. Jackson et al. (Exhibit 6);
- 7. U.S. Patent No. 5,962,521, issued October 5, 1999 to Paul F. Jackson et al. (Exhibit 7);
- U.S. Patent No. 5,968,915, issued October 19, 1999 to Paul
   F. Jackson et al. (Exhibit 8);
- 9. U.S. Patent No. 5,981,209, issued November 9, 1999 to Barbara S. Slusher et al. (Exhibit 9);
- 10. U.S. Patent No. 6,011,021, issued January 4, 2000 to Barbara S. Slusher et al. (Exhibit 10);
- 11. U.S. Patent No. 6,017,903, issued January 25, 2000 to Barbara S. Slusher et al. (Exhibit 11);
- 12. U.S. Patent No. 6,025,344, issued February 15, 2000 to Paul
  F. Jackson et al. (Exhibit 12);
- 13. U.S. Patent No. 6,025,345, issued February 15, 2000 to Paul
  F. Jackson et al. (Exhibit 13);
- 14. U.S. Patent No. 6,046,180, issued April 4, 2000 to Paul F.
   Jackson et al. (Exhibit 14);
- 15. U.S. Patent No. 6,054,444, issued April 25, 2000 to Paul F.
   Jackson et al. (Exhibit 15);
- 16. U.S. Patent No. 6,121,252, issued September 19, 2000 to Paul F. Jackson et al. (Exhibit 16);
- 17. U.S. Patent No. 6,271,245, issued August 7, 2001 to Paul F.
   Jackson et al. (Exhibit 17);
- 18. U.S. Patent No. 6,288,046, issued September 11, 2001 to
   Paul F. Jackson et al. (Exhibit 18);
- 19. U.S. Patent No. 6,348,464, issued February 19, 2002 to Paul
  F. Jackson et al. (Exhibit 19);
- 20. U.S. Patent No. 6,372,726, issued April 16, 2002 to Barbara
  S. Slusher et al. (Exhibit 20);
- 21. U.S. Patent No. 6,384,022, issued May 7, 2002 to Paul F. Jackson and Barbara S. Slusher (Exhibit 21);
- 22. U.S. Patent No. 6,395,718, issued May 28, 2002 to Barbara

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- S. Slusher and Rena Lapidus (Exhibit 22);
- 23. U.S. Patent No. 6,413,948, issued July 2, 2002 to Barbara
  S. Slusher et al. (Exhibit 23);
- 24. U.S. Patent No. 6,452,044, issued September 17, 2002 to Paul F. Jackson et al. (Exhibit 24);
- 25. U.S. Patent No. 6,458,775, issued October 1, 2002 to Paul F. Jackson et al. (Exhibit 25);
- 26. U.S. Patent No. 6,479,471, issued November 12, 2002 to Paul
  F. Jackson et al. (Exhibit 26);
- 27. U.S. Patent No. 6,586,623, issued July 1, 2003 to Takashi Tsukamoto et al. (Exhibit 27);
- 28. Barbara S. Slusher and Krystyna Wozniak, U.S. Serial No. 09/866,729, filed May 30, 2001, U.S. Publication No. 20020013295, published January 31, 2002 (Exhibit 28);
- 29. Paul F. Jackson et al., U.S. Serial No. 09/866,758, filed
  May 30, 2001, U.S. Publication No. 20020019430, published
  February 14, 2002 (Exhibit 29);
- 30. Paul F. Jackson et al., U.S. Serial No. 09/880,861, filed
  June 15, 2001, U.S. Publication No. 20010044459, published
  November 22, 2001 (Exhibit 30);
- 31. Takashi Tsukamoto et al., U.S. Serial No. 10/046,917, filed January 17, 2002, U.S. Publication No. 20030105088, published June 5, 2003 (Exhibit 31);
- 32. Barbara S. Slusher et al., U.S. Serial No. 10/056,079, filed January 28, 2002, U.S. Publication No. 20020151503, published October 17, 2002 (Exhibit 32);
- 33. Barbara S. Slusher et al., U.S. Serial No. 10/119,828,
  filed April 11, 2002, U.S. Publication No. 20030064912,
  published April 13, 2003 (Exhibit 33);
- 34. Paul F. Jackson et al., U.S. Serial No. 10/164,553, filed June 10, 2002, U.S. Publication No. 20030083374, published May 1, 2003 (Exhibit 34);
- 35. Barbara S. Slusher et al., U.S. Serial No. 10/209,011,

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- filed August 1, 2002, U.S. Publication No. 20030017965, published January 23, 2003 (Exhibit 35);
- 36. Takashi Tsukamoto et al., U.S. Serial No. 10/431,462, filed May 8, 2003, U.S. Publication No. 20030216468, published November 20, 2003 (Exhibit 36);
- 37. U.S. Patent No. 5,773,292, issued June 30, 1998 to Neil H. Bander (Exhibit 37);
- 38. U.S. Patent No. 6,649,163, issued November 18, 2003 to Neil H. Bander (Exhibit 38);
- 39. Neil H. Bander, U.S. Serial No. 09/929,543, filed August 13, 2001, U.S. Publication No. 20020015704, published February 7, 2002 (Exhibit 39);
- 40. Neil H. Bander, U.S. Serial No. 09/929,546, filed August 13, 2001, U.S. Publication No. 20030031673, published February 13, 2003 (Exhibit 40);
- 41. David M. Nanus et al., U.S. Serial No. 10/160,994, filed May 30, 2002, U.S. Publication No. 20030007974, published January 9, 2003 (Exhibit 41);
- 42. Gerald P. Murphy et al., U.S. Serial No. 10/428,360, filed May 1, 2003, U.S. Publication No. 20040024188, published February 5, 2004 (Exhibit 42);
- 43. PCT International Application No. PCT/US02/17298, filed May 30, 2002, International Publication No. WO 02/096460 A1, published December 5, 2002 (Exhibit 43);
- 44. PCT International Application No. PCT/US02/17068, filed May 30, 2002, International Publication No. WO 02/098897 A2, published December 12, 2002 (Exhibit 44);
- 45. U.S. Patent No. 5,935,818, issued August 10, 1999 to Ron S. Israeli et al. (Exhibit 45);
- 46. U.S. Patent No. 6,569,432 B1, issued May 27, 2003 to Ron S. Israeli et al. (Exhibit 46);
- 47. Pending claims in Ron S. Israeli et al., U.S. Serial No. 08/403,803, filed March 17, 1995 (Exhibit 47);

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- 48. Pending claims in Ron S. Israeli et al., U.S. Serial No. 08/470,735, filed June 6, 1995 (Exhibit 48);
- 49. Pending claims in Ron S. Israeli et al., U.S. Serial No. 09/724,026, filed November 28, 2000 (Exhibit 49);
- 50. Pending claims in Ron S. Israeli et al., U.S. Serial No. 09/990,595, filed November 21, 2001 (Exhibit 50);
- 51. Pending claims in Ron S. Israeli et al., U.S. Serial No. 08/481,916, filed June 7, 1995 (Exhibit 51);
- 52. Pending claims in Ron S. Israeli et al., U.S. Serial No. 10/012,169, filed October 24, 2001 (Exhibit 52);
- 53. Pending claims in Ron S. Israeli et al., U.S. Serial No. 10/443,694, filed May 21, 2003, U.S. Publication No. 20040001846, published January 1, 2004 (Exhibit 53);
- 54. Ron S. Israeli et al., U.S. Serial No. 10/614,625, filed July 2, 2003 (Exhibit 54);
- 55. Preliminary Amendment filed July 2, 2003 in connection with U.S. Serial No. 10/614,625 (i.e., reference 54) (Exhibit 55);
- 56. Pending claims in Ron S. Israeli et al., U.S. Serial No. 08/894,583, filed February 23, 1998 (Exhibit 56);
- 57. Pending claims in Ron S. Israeli et al., U.S. Serial No. 10/751,346, filed January 2, 2004 (Exhibit 57);
- 58. PCT International Application No. PCT/US96/02424, filed February 23, 1996, International Publication No. WO 96/26272, published August 29, 1996 (Exhibit 58);
- 59. Sharief, F.S., Lee, H., Leuderman, M.M., Lundwall, A., Deaven, L.L., Lee, C.L. and Li, S.S. (1989) Human prostatic acid phosphatase: cDNA cloning, gene mapping and protein sequence homology with lysosomal acid phosphatase. Biochem. Biophys. Res. Commun. 160: 79-86;
- 60. Wright, Jr., G.L, Feng, Q., Beckett, M.L., Lopes, D. and Gilman, S.C. (1990) Characterization of a new prostate carcinoma-associated marker: 7E11-C5. Antibody,

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Immunoconjugates and Radiopharmaceuticals 3: 89 (Abstract 193); and

61. Young, R.A. and Davis, R.W. (1983) Efficient isolation of genes by using antibody probes. Proc. Natl. Acad. Sci. USA 80: 1194-1198.

The Examiner is respectfully requested to make these references of record in the present application by initialing and dating the PTO 1449 form provided as **Exhibit A**, and returning a copy of the executed form to applicants' representatives with the next Communication concerning this application.

Applicants note that the above-cited references, 47-52 and 54, 56 and 57, are patent applications that are related to the present application and which have neither been issued as patents nor published. Reference 47 is a national stage counterpart of, and references 48-50 are continuations of, PCT International Application No. PCT/US93/10624, published under International Publication No. WO 94/09820. A copy of International Publication No. WO 94/09820 was submitted to the Patent Office as reference 4 in an Information Disclosure Statement filed on July 11, 1997 in connection with the present application. Thus, pursuant to 37 C.F.R. \$1.98(c), copies of references 47-50 are not provided herein as they are cumulative. However, pursuant to 37 C.F.R. \$1.98(a)(2), copies of the claims pending in references 47-50 are provided as Exhibits 47-50, respectively.

Reference 51 is a continuation of U.S. Serial No. 08/325,553. A copy of U.S. Serial No. 08/325,553, now U.S. Patent No. 5,538,866, was submitted to the Patent Office as reference 3 in an Information Disclosure Statement filed on July 11, 1997 in connection with the present application. Thus, pursuant to 37 C.F.R. \$1.98(c), a copy of reference 51 is not provided herein as it is cumulative. However, pursuant to 37 C.F.R. \$1.98(a)(2), a

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copy of the claims pending in reference 51 is provided as **Exhibit** 51.

References 52 and 53 are continuations of U.S. Serial No. 08/705,477, now U.S. Patent No. 6,569,432, a copy of which is enclosed as **Exhibit 46**. Pursuant to 37 C.F.R. §1.98(c), copies of references 52 and 53 are not provided as they are cumulative. However, pursuant to 37 C.F.R. §1.98(a)(2), copies of the claims pending in references 52 and 53 are provided as **Exhibits 52** and **53**, respectively.

Reference 54 (U.S. Serial No. 10/614,625) is a continuation—inpart of U.S. Serial No. 10/433,694, which is a continuation of U.S. Serial No. 08/705,477, now U.S. Patent No. 6,569,432, a copy of which is enclosed as **Exhibit 46**. Applicants attach hereto as **Exhibit 54** a copy of the specification and claims (corresponding to U.S. Serial No. 08/705,477) filed for U.S. Serial No. 10/614,625, together with a July 2, 2003 Preliminary Amendment (copy attached as **Exhibit 55**) which amended the specification and claims of U.S. Serial No. 10/614,625. The amended claims recited in this Preliminary Amendment are currently pending.

Reference 56 is a national stage counterpart of, and reference 57 is a continuation of, PCT International Application No. PCT/US96/02424, published under International Publication No. WO 96/26272, a copy of which is enclosed as **Exhibit 58**. Pursuant to 37 C.F.R. §1.98(c), copies of references 56 and 57 are not provided herein as they are cumulative. However, pursuant to 37 C.F.R. §1.98(a)(2), copies of the claims pending in references 56 and 57 are provided as **Exhibits 56** and **57**, respectively.

Applicants also note that references 59, 60 and 61 had previously been cited (as references 25, 34 and 35 respectively) and copies provided to the Examiner in an Information Disclosure Statement

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filed July 11, 1997. However, applicants have noticed that the listing of these three references on the accompanying PTO-1449 form did not include their publication dates which, in other instances, has resulted in the Examiner not considering such references. Applicants therefore cite these references again in the instant Information Disclosure Statement, with the reference dates included on the attached PTO-1449 form (Exhibit A). Copies of these references are not provided as they were previously submitted in the July 11, 1997 Information Disclosure Statement.

Further to the above, applicants direct the Examiner's attention to the article by Su et al. entitled "Alternatively Spliced Variants of Prostate-specific Membrane Antigen RNA: Ratio of Expression as a Potential Measurement of Progression" (Cancer Research 55: 1441-1443, 1995), dealing with a splice variant of prostate specific membrane antigen, which was cited by applicants Supplemental Information Disclosure Statement Certification Pursuant To 37 C.F.R. §1.97 (e)(1), filed May 7, 2002 in the present application. The first named author of the subject paper, Dr. Sai L. Su, has alleged that he was a coinventor of claims directed to a splice variant of prostate specific membrane antigen contained in U.S. Patent No. 5,935,818 to Israeli et al. which issued August 10, 1999 and which is assigned to the Assignee of the present case. The subject matter of the claims of U.S. Patent No. 5,935,818 is not, however, the subject matter claimed in the present application. Applicants' representatives are investigating the claim raised by Dr. Su.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone either of them at the number provided below.

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Pursuant to 37 C.F.R. \$1.97(c)(2) and 1.17(p), a fee of \$180.00 is required for filing this Supplemental Information Disclosure Statement, and a check for this amount is enclosed. additional fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents P.O Box 1450, Alexandria

VA 22313-1450

ch C. Faley John

Reg. No. 28,678 Mark A. Farley Reg. No. 33,170 John P. White

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#### U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No.
41426-C
/JPW/MAF/AJD
Applicant(s)
Ron S. Israeli et al.

## INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)

Filing Date
June 6, 1995

Art Unit
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#### U.S. PATENT DOCUMENTS

Examiner Initials	Exh No.		Doc	u me	nt N	umb	er		<b>Date</b> 09/30/97	Name Jackson & Slusher	Class	Subclass	Filing Date If Appropriate
	1 -	5	6	7	2	5	9	2					
	2	5	7	9	5	8	7	7	08/18/98	Jackson			
	3	5	8	0	4	6	0	2	09/08/98	Slusher et al.		RE	CEIVED
	4	5	8	6	3	5	- 3	6	01/26/99	Jackson et al.			
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	7	5	9	6	2	5	2	1	10/05/99	Jackson et al.			
	8	5	9	6	8	9	1	5	10/19/99	Jackson et al.			
	9	5	9	8	1	2	0	9	11/09/99	Slusher et al.			
	10	6	0	1	1	0	2	1	01/04/00	Slusher et al.			

#### FOREIGN PATENT DOCUMENTS

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	43~	/02	0	9	6	4	6	0	12/05/02	PCT					
	44	/02	0	9	8	8	9	7	12/12/02	PCT					
	58 .	9	6	2	6	2	7	2	08/29/96	PCT					

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Sharief, F.S., Lee, H., Leuderman, M.M., Lundwall, A., Deaven, L.L., Lee, C.L. and Li, S.S. (1989) Human prostatic acid phosphatase: cDNA cloning, gene mapping and protein sequence homology with lysosomal acid phosphatase. Biochem. Biophys. Res. Commun. 160: 79-86;

Wright, Jr., G.L, Feng, Q., Beckett, M.L., Lopes, D. and Gilman, S.C. (1990) Characterization of a new prostate carcinoma-associated marker: 7E11-C5. Antibody,

Immunoconjugates and Radiopharmaceuticals 3: 89 (Abstract 193); and Young, R.A. and Davis, R.W. (1983) Efficient isolation of genes by using antibody probes. Proc. Natl. Acad. Sci. USA 80: 1194-1198.

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#### **EXAMINER**

## DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Form PTO-1449

# U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Atty. Docket No. 41426-C /JPW/MAF/AJD Serial No. 08/466,381

Applicant(s)

Ron S. Israeli et al.

Filing Date
June 6, 1995

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#### **U.S. PATENT DOCUMENTS**

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**EXAMINER** 

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<sup>\*</sup>EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Form PTO-1449

## U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

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**Atty. Docket No.** 41426-C /JPW/MAF/AJD Serial No. 08/466,381

Applicant(s)

Ron S. Israeli et al.

Filing Date June 6, 1995 Art Unit 1647

## U.S. PATENT DOCUMENTS

Examiner Initials	Exh No.		Doc	ume	nt N	umt	er :		Date	Name	Class	Subclass	Filing Date If Appropriate
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**EXAMINER** 

DATE CONSIDERED

<sup>\*</sup>EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.